

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003D-0051]

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**International Cooperation on Harmonization of Technical Requirements for
Registration of Veterinary Medicinal Products; Guidance for Industry on Pre-
Approval Information for Registration of New Veterinary Medicinal Products
for Food-Producing Animals With Respect to Antimicrobial Resistance (VICH
GL27); Availability**

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry (#144) entitled "Pre-Approval Information for Registration of New Veterinary Medicinal Products for Food-Producing Animals With Respect to Antimicrobial Resistance" (VICH GL27). This guidance has been developed for veterinary use by the International Cooperation on Harmonization of Technical Requirements for Registration of Veterinary Medicinal Products (VICH). This VICH guidance document is an initial step in developing harmonized technical guidance in the European Union, Japan, and the United States for approval of therapeutic antimicrobial veterinary medicinal products intended for use in food-producing animals with regard to characterization of antimicrobial resistance selection in bacteria of human health concern. The guidance outlines the types of studies and data which are recommended for assessing the potential for resistance to develop in association with the use of antimicrobial drugs in food-producing animals.

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Communications Staff (HFV-12), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests.

Submit electronic or written comments at any time on the guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. Comments should be identified by the docket number found in brackets in the heading of this document. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: William T. Flynn, Center for Veterinary Medicine (HFV-2), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 301-827-4514, e-mail: wflynn@cvm.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote the international harmonization of regulatory requirements. FDA has participated in efforts to enhance harmonization and has expressed its commitment to seek scientifically based harmonized technical procedures for the development of pharmaceutical products. One of the goals of harmonization is to identify and then reduce differences in technical requirements for drug development among regulatory agencies in different countries.

FDA has actively participated in the International Conference on Harmonization of Technical Requirements for Approval of Pharmaceuticals for Human Use for several years to develop harmonized technical requirements for the approval of human pharmaceutical and biological products among the European Union, Japan, and the United States. The VICH is a parallel initiative for veterinary medicinal products. The VICH is concerned with developing harmonized technical requirements for the approval of veterinary medicinal products in the European Union, Japan, and the United States, and includes input from both regulatory and industry representatives.

The VICH Steering Committee is composed of member representatives from the European Commission, European Medicines Evaluation Agency; European Federation of Animal Health; Committee on Veterinary Medicinal Products; the U.S. FDA; the U.S. Department of Agriculture; the Animal Health Institute; the Japanese Veterinary Pharmaceutical Association; the Japanese Association of Veterinary Biologics; and the Japanese Ministry of Agriculture, Forestry and Fisheries.

Four observers are eligible to participate in the VICH steering committee: One representative from the Government of Australia/New Zealand, one representative from the industry in Australia/New Zealand, one representative from the Government of Canada, and one representative from the industry of Canada. The VICH Secretariat, which coordinates the preparation of documentation, is provided by the Confédération Mondiale de L'Industrie de la Santé Animale (COMISA). A COMISA representative also participates in the VICH Steering Committee meetings.

II. Guidance on Antimicrobial Resistance

In the **Federal Register** of June 12, 2003 (68 FR 35234), FDA published the notice of availability of the VICH draft guidance, giving interested persons until July 14, 2003, to submit comments. After consideration of comments received, the draft guidance was changed in response to the comments and submitted to the VICH Steering Committee. At a meeting held on October 7 and 8, 2003, the VICH Steering Committee endorsed the guidance for industry, VICH GL27.

The VICH guidance document is an initial step in developing harmonized technical guidance in the European Union, Japan, and the United States for approval of therapeutic antimicrobial veterinary medicinal products intended for use in food-producing animals with regard to characterization of antimicrobial resistance selection in bacteria of human health concern.

This guidance document outlines the types of studies and data that may be used to characterize the potential for resistance to develop in the target animal when an antimicrobial drug product is used under the proposed conditions. This includes information which describes the drug substance, drug product, nature of the resistance, and potential exposure of gut flora in the target animal species. This information may be used as part of an overall assessment of the potential impact of the product on human health. Information collection is covered under the Office of Management and Budget control number 0910–0032.

III. Significance of Guidance

This guidance document, developed under the VICH process, has been revised to conform to FDA's good guidance practices regulation (21 CFR 10.115). For example, the document has been designated "guidance" rather

than “guideline.” Because guidance documents are not binding, mandatory words such as “must,” “shall,” and “will” in the original VICH document have been substituted with “should” or “recommend.”

This VICH guidance document is consistent with the agency’s current thinking, on the type of pre-approval information that should be considered for new veterinary medicinal products for food-producing animals with regard to characterization of antimicrobial resistance selection in bacteria of human health concern. This guidance does not create or confer any rights for or on any person and will not operate to bind FDA or the public. An alternative method may be used as long as it satisfies the requirements of applicable statutes and regulations.

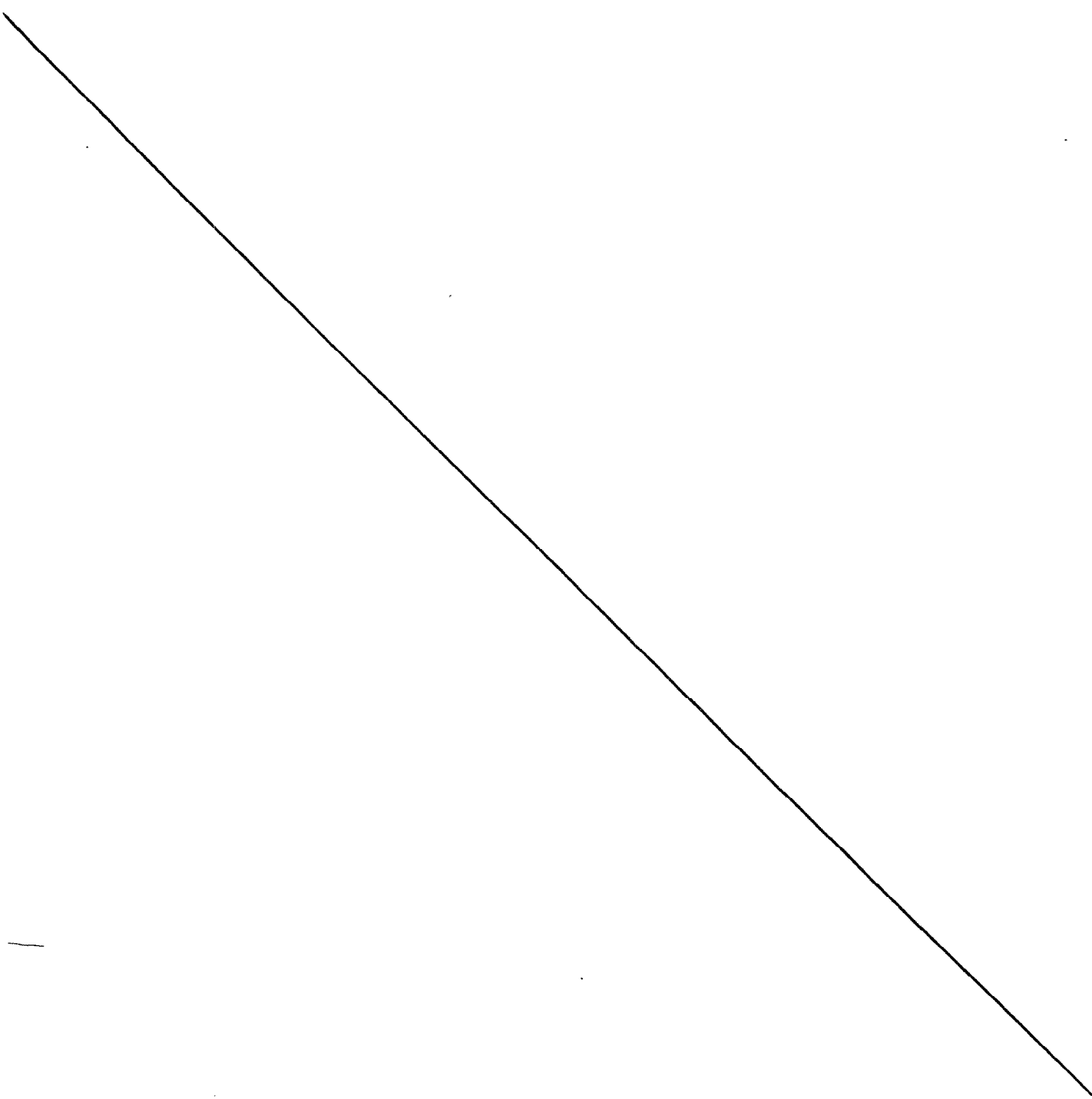
IV. Comments

As with all of FDA’s guidances, the public is encouraged to submit written or electronic comments pertinent to this guidance. FDA will periodically review the comments in the docket and where appropriate, will amend the guidance. The agency will notify the public of any such amendments through a notice in the **Federal Register**.

Interested persons may submit written comments to the Division of Dockets Management (see **ADDRESSES**) regarding this guidance document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments should be identified with the docket number found in the brackets in the heading of this document. A copy of the guidance document and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

V. Electronic Access

Persons with Internet access may obtain a copy of the guidance document entitled "Pre-Approval Information for Registration of New Veterinary Medicinal Products for Food-Producing Animals with Respect to Antimicrobial



Resistance" (VICH GL-27) may be obtained on the Internet from the CVM
Home Page at <http://www.fda.gov/cvm>.

Dated: _____

4/19/04
April 19, 2004.



Jeffrey Shuren,
Assistant Commissioner for Policy.

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